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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CONFIRMATION NO.	
10/058,291	01/30/2002	James L. Hartley	IVGN 127.8 CON 3302	
	7590 04/15/200 CORPORATION	EXAMINER		
C/O INTELLEY	· <del>-</del>	KETTER, JAMES S		
P.O. BOX 5205 MINNEAPOLI	-		ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summany		Application	on No.	o. Applicant(s)				
		10/058,29	91	HARTLEY ET AL.				
Office Action Summary			•	Art Unit				
		James S.		1636				
Period fo	The MAILING DATE of this communication or Reply	appears on the	e cover sheet with the d	correspondence ad	ddress			
WHIC - Exter after - If NC - Failu Any (	ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CFF SIX (6) MONTHS from the mailing date of this communication period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by streply received by the Office later than three months after the med patent term adjustment. See 37 CFR 1.704(b).	DATE OF THE ALL STATES AND ALL STATE	HIS COMMUNICATION ent, however, may a reply be tir ill expire SIX (6) MONTHS from lication to become ABANDONE	N. nely filed the mailing date of this of (35 U.S.C. § 133).				
Status								
1) 又	Responsive to communication(s) filed on 2	6 March 2009						
•			on-final					
3)□	· <del></del>							
اللات	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
	closed in accordance with the practice und	ei Lx parte Qu	ayle, 1955 C.D. 11, 40	JJ O.G. 213.				
Dispositi	on of Claims							
4)🛛	Claim(s) <u>113-124</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.							
	6)⊠ Claim(s) <u>113-124</u> is/are rejected.							
· ·	Claim(s) is/are objected to.							
•	Claim(s) are subject to restriction an	nd/or election r	equirement					
٥,١	and daspess to receive and	14, 51 5155115111	oquii oii i oii i					
Applicati	on Papers							
9)	The specification is objected to by the Exam	niner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
2)  Notic 3)  Inform	<b>t(s)</b> e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date		4) Interview Summary Paper No(s)/Mail Di 5) Notice of Informal F 6) Other:	ate				

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 113-124 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record set forth in the previous Office Action. This is a new matter rejection.

At page 4 of the amendment filed 26 March 2009, Applicants argue that they have amended the independent claim to more clearly define the subject matter of the claims.

Applicants then explain that the claim has been amended to recite an origin of replication functional in prokaryotes, first and second positive selection markers functional in prokaryotes, and that the first and second recombination sites do not recombine with each other. However, this merely sidesteps the issue, that there was no support for the genus, as claimed now or previously, in the specification as filed. Applicants then quote the Federal Circuit:

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus ..." (Univ. of California v. Eli Lilly & Co., 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1996)). However, the concept of the particular generic types of components of the invention in the recited order was not presented in the specification or drawings as filed; rather, it has been imputed after filing. Any particular example, embodiment or drawing might give rise to an infinitude of such concepts or schematics. However, one of skill would not have known or understood which one was intended by

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Applicants. As such, no particular genus, based on such a concept, would have been recognized by one of skill as being in possession of Applicants at the time of filing. The instant claims, therefore, are drawn to new matter.

This is an RCE of applicant's earlier Application No. 10/058,291. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK 15 April 2009

/James S. Ketter/ Primary Examiner, Art Unit 1636